APR - 5 2001

K010900
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510(k) SUMMARY
[Submitted pursuant to 21 CFR 807.87 (h).]

1. Submitter Information:

Submitter:	Medstone International, Inc. 100 Columbia, Suite 100 Aliso Viejo, CA 92656
Telephone:	(949) 448-7700
Facsimile:	(949) 448-7880
Contact Person:	Ronald H. Bergeson VP, Regulatory Affairs/Quality Assurance
Date Prepared:	March 23, 2001

2. Device:

Trade/Proprietary Name:	Medstone STS-T Lithotripter with C-Arm
Common/Usual Name:	Extracorporeal shock-wave lithotripter (ESWL)
Classification Name:	Extracorporeal shock-wave lithotripter

3. Intended Use:

The Medstone STS-T is indicated for use in the fragmentation of upper urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones.

4. Predicate Device:

Medstone STS-T Lithotripter with U-Arm and the Healthtronics Lithotron

5. Device Description:

The STS-T Lithotripter is a therapeutic device comprised of an x-ray (c-Arm) localizing system and the shockwave generator. This system is used to localize and fragment upper urinary tract stones.

6. Comparison of Non-Clinical Performance Data:

Localization deviation was determined to be 3mm which is a value within the requirements stated in FDA's "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" (August 2000).

7. Conclusions Drawn From Non-Clinical Tests:

The Medstone STS-T Lithotripter with C-Arm and the predicate devices from Medstone and Healthtronics perform the same function, in the same environment and have the same intended use.

A comparison of device specifications and principals of operation, primarily localization, indicates that no new questions of efficacy, or substantial risk are raised.

Validation tests indicate the device with C-Arm localizes with an accuracy of 3mm, which is the same Medstone requirement for the STS-T Lithotripter with U-Arm, and the STS Lithotripter, and is within FDA's requirement.

Therefore, the Medstone STS-T Lithotripter with C-Arm is substantially equivalent to other predicate devices, notably the Medstone STS-T Lithotripter with U-Arm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Mr. Ronald H. Bergeson
VP, Regulatory Affairs/Quality Assurance
Medstone International, Incorporated
100 Columbia, Suite 100
ALISO VIEJO CA 92656-4114

Re: K010900
STS-T Lithotripter: Addition of C-Arm
(as option to existing U-Arm)
Dated: March 23, 2001
Received: March 26, 2001
Regulatory Class: II
21 CFR §876.5990/Procode: 78 LNS

Dear Mr. Bergeson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

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3. INDICATIONS FOR USE SHEET

INDICATIONS FOR USE

510(k) Number (if known): K010900

Device Name: STS-T Lithotripter

Indications for Use:

The Medstone STS-T is indicated for use in the fragmentation of upper urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguros

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010900

Prescription Use ✓

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)